UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,632	02/04/2002	Corey S. Goodman	B94-002-8	3003

20350 7590 09/30/2005

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
WANG, CHANG YU	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,632	GOODMAN ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SDP

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 14, 15 and 23, drawn to polypeptides, classified in class 530, subclass 350.

II. Claims 6 and 16, drawn to an antibody, classified in class 424, subclass 130.1.

III. Claims 7, 8 and 10, 17-19, drawn to polynucleotides, vectors and host cells for making polypeptides, classified in class 536, subclass 23.1 or class 435, subclass 69.1.

IV. Claim 9, drawn to a transgenic rodent, classified in for example class 800, subclass 3.

V. Claims 11 in part and 20 in part, drawn to a method of identifying a pharmacological agent useful in the diagnosis of disease associated with the binding of a semaphorin to a semaphorin receptor, classified in for example class 435, subclass 7.21.

VI. Claims 11 in part and 20 in part, drawn to a method of identifying a pharmacological agent useful in the treatment of disease associated with the binding of a semaphorin to a semaphorin receptor, classified in for example class 435, subclass 7.21.

VII. Claims12 and 21, drawn to a method of diagnosing a patient for a predisposition to neurological disease associated with a genetic locus, classified in for example class 424, subclass 9.1.

VIII. Claims 13 and 22, drawn to a method of treating a patient with neurological injury or disease or a pathological viral infection, classified in for example class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II and III are patentably distinct products and related as follows:

Inventions I and II are related as products. The products are distinct each from the other as the products are comprised of divergent structure, effects and function. An antibody is composed of a pair of heavy chain and light chain of peptides, Fab fragments, for antigen-binding, and a pair of complement binding domain (Fc fragment). The use for antibody is various, for example the antibody can be used to detect a protein and also for immunotherapy as a therapeutical agent. Although the protein can be used as a therapeutical agent, the effects of the protein treatment are very distinct from those of antibodies because antibodies tend to be used as antagonists.

Inventions I and III are related as products. The products are distinct each from the other as the products are comprised of divergent structure, effects and function, for example nucleic acids, peptides and cells or organisms.

The polynucleotides and vectors in the group III and polypeptides in the group I are patentably distinct inventions for the following reasons. First, polynucleotides and polypeptides are structurally distinct molecules. The former are the molecules consisting of purine and pyrimidine, and the later are the molecules consisting of amino acids. A polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The different combination of purine and pyrmidine of group III can generate a diverse range of sequences of polypeptides in the group I. For example, a point mutation of polynucleotides in the group III can totally change the composition of polypeptides in the group I. Second, the biochemical properties of polypeptides are quite different from those of polynucleotides. The polypeptides can be isolated and analyzed using affinity chromatography or mass spectrophotometry. In addition, they are sensitive to proteinase, which is very different from polynucleotides that are sensitive to DNAase. Third, the biological function and use of polynucleotides are very different from those of polypeptides. Polynucleotides can be modified and used as a probe labeling with different fluorescence conjugates or radioisotopes to hybridize or detect the message of DNA/RNA. On the other hand, polypeptides function as biological agents that are more involved in targeting, recognition, trafficking, anchoring, and activity

execution and regulation. The cellular distribution of polypeptides is very different from that of polynucleotides. Polypeptides could be located on the plasma membrane to function as a receptor to receive the signals. They could be also located in the cytosol or nucleus to regulate other proteins or DNA activity. In addition, each of the polypeptides or polynucleotides has a unique structural feature, which requires a unique search of the prior art. The Groups I and III differ in structure and function as they are composed of divergent amino acids and have different biological functions. A reference to one element would not constitute a reference to another. Thus, Groups I, II and III are patentably distinct.

3. Inventions I and V, VI, VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the nucleic acids and peptides can be practiced with alternative nucleic acids or peptides and the products as claimed can be used alternatively in a method of treatment, a method of making antibodies, a method of screening compounds, and a method for detecting compositions.

4. Inventions IV, V, VI, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP

§ 806.04, MPEP § 808.01). In this instant case, first, the procedures, materials and equipments used in the method of identifying a molecule for diagnosis (Groups V and VII) are very different from those in treatment of disease (Groups VI and VIII). For example, in the Group VII, the technology and materials used for diagnosing a predisposition to neurological disorders associated with a genetic locus focus on the DNA and in situ hybridization using chromosomal markers for detection the linkage between disorders and the genes or short tandem repeat nucleic acid primers for linkage study. However, the treatment for a disease basically could be a protein therapy, antisense, siRNA or other antagonist approaches. Apparently, the procedures, materials and the equipments involved are very different. Second, the patient populations are very distinct in the method of diagnosis disease from in the method of treating disease. The health and physiological conditions are very distinct. For example, the mental status, behavior, symptoms and the medication conditions as well as the etiology and pathology are very different. Furthermore, the procedures and materials required for generating a transgenic rodent (Group IV) are also very different from those of Groups V-VIII mentioned above.

5. Thus, the inventions IV, V, VI, and VIII are patentably distinct.

6. Furthermore, in addition to the election of one of the above VIII groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

i. A single designated amino acid composition selected from SEQ ID NOs: 1-52 and 67-91 needs to be elected.

ii. A single designated antibody specifically binding to a peptide needs to be elected if Group II is elected. Applicant is also required to identify the corresponding peptide.

iii. A single designated nucleotide sequence needs to be elected if Group III is elected.

iv. A single designated molecule selected from A) semaphorin or B) semaphorin receptor needs to be elected if any one of Groups I-VIII is elected.

7. The inventions are distinct, each from the other because of the following reasons:

8. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated as i-iv constitute patentably distinct inventions for the following reasons. Each of the polypeptides, antibodies and polyucleotides has a unique structural feature which requires a unique search of the prior art. The inventions indicated as i-iv differ in structure and function as they are composed of divergent amino acids, antibodies and polynucleotides, and also the use for each molecule are different, which they are differentially able to bind or mediate bological functions. Therefore, groups i-

iv constitute very divergent subject matters. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules and neurological conditions in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-VIII and a single molecular embodiment for each of designated groups i-iv to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither Groups I-VIII nor groups i-iv are species election requirements; rather each of Groups I-VIII and groups i-iv are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups. It is noted that while one of groups i-iv may not be applicable to one of Groups I-VIII, applicant must elect one of each in order to be fully compliant.

Species Election

11. This application contains claims directed to the following patentably distinct species of the claimed invention:

The species of the patient's condition are as follows:

A) Neurological injury, B) Neurological disease, or C) Pathological viral infection.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. The claims are deemed to correspond to the species listed above in the following manner:

If Group VIII is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the patient's condition from A) Neurological injury, B) Neurological disease, or C) Pathological viral infection recited in claims 13 and 22 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 13 and 22 are generic.

16. The species listed above are patentably distinct for the following reasons:

These species are distinct because they are different diseases. Each specific species differs with respect to its etiology and potential molecular mechanisms contributed to its pathological conditions. The pathology and etiologies of neurological injury are very different from those of neurological disease and pathological viral infection. The patient populations in each pathological condition are also very different. The physiological conditions of patients and the populations for patients with neural injury, neurological diseases or pathological viral infection are distinct. It requires different diagnoses, equipments, steps and treatments for these different groups of patients. Therefore, each species is patentably distinct.

17. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

18. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to

maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

20. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

21. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-

Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
September 22, 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER